

# NTP Process Listening Session

November 29, 2011

George Cruzan, PhD, DABT

# Prior to RoC 12

- Dr. Birnbaum presented to Congressional Committee – NTP evaluated more than 600 substances and successfully listed all but 3.
- Emphasis is on Listing, not objective evaluation
- Should be noted that NTP staff recommended listing the other 3, but were vetoed by BSC.

# RoC 12

- NTP took away ability of BSC to veto staff conclusions.
- NTP allowed public comments, but completely ignored them.
  - Expert Panels did not consider them
  - Interagency Panel given public comments only 4 days before voting
  - Staff ignored comments from BSC
  - Staff not even aware of the content of public comments
  - Response to public comments only after completion of RoC; dismissed all but minor wording changes

# Proposed RoC 13

- Eliminate Interagency vote
- Eliminate Expert Panel
- Eliminate Background Document
- Optional to obtain comments from BSC
- No written response to public comments
- NTP writes the document; NTP decides if the document is correct

# Relevance of Process

- Transparency of process does not provide transparency of substance evaluation.
- NTP needs to seriously examine NAS chapter 7 for process of evaluation.
- Short-timeframes for public comment and submission to BSC indicates NTP really does not want thoughtful input.

# Objectives

- Emphasis from NTP needs to be on modernizing criteria for listing using current understanding of cancer development and weight of evidence
- Objective should be to list chemicals that are likely to be carcinogenic risk to humans.
  - Currently no distinction between those that are likely to be carcinogenic and those have a slight possibility of being carcinogenic to humans.

# Review of Assessments

- NTP (or OMB) should appoint a truly independent editor or arbitrator. (Not one who will always defer to NTP)
- NTP document would be submitted to editor, who would solicit comments (from experts the editor selects and the public). The editor reviews comments and notifies NTP if minor or major revisions are needed for acceptance. The editor has final say on acceptance of revised NTP document.

# Summary

- NTP needs to develop a transparent method for evaluation, modernize classification criteria for current understanding of cancer development, provide a truly independent evaluation process.